NSC: 676693

Executive Plaza North, Room 831

CAS: 156274-19-0

6130 Executive Blvd., Rockville, MD 20852

Create Date:

6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

Supplier MSDS N

Last Revised:

1. Company Identification

In Case of Emergency Call:

Decontamination Procedures

Pharmaceutical Resources Branch, (301)-496-8780

Material Safety Data Sheets

Drug Synthesis and Chemistry Branch, (301)-496-8795

Toxicity Data

Toxicology Branch,(301)-496-\$777

Additional Information

2. Chemical Product and Composition

Chemical Name

Common Name

Synonyms

Molecular Weight

281

Molecular Formula

C16H11NO2S

Composition

This material consists solely of 676693

Additional Information

3. Hazards Identification

RTECS Index

Summary of Risks

To the best of our knowledge, the toxicological properties of this material

have not yet been fully investigated.

Known Carcinogen

This compound is not listed in the OSHA, IARC or NTP literature as a

carcinogen or cancer suspect agent.

Medical Conditions Aggravated by

Contact

Unknown

Target Organs

The target organs of toxicity are not known at this time.

Relevant Routes of Entry

Inhalation, ingestion, and skin/eye contact.

Acute Effects

The acute effects of exposure to this material in the workplace are not

Chronic Effects

known at this time.

The chronic effects of exposure to this material in the workplace are not known at this time.

Eye Contact

The effects of eye contact with this material are unknown.

Skin Contact Inhalation

The effects of skin contact with this material are unknown.

Ingestion

The effects of inhalation of this material are unknown.

The effects of ingestion of this material are unknown.

SHRADER 539CC

Developmental Therapeutics Program, National Cancer Institute

Executive Plaza North, Room 831

6130 Executive Blvd., Rockville, MD 20852

NSC: 676693

CAS: 156274-19-0

Supplier MSDS

Create Date: Last Revised: 6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

Known Hazards

None known

Additional Information

4. First Aid Measures

Flush with running water for at least 15 minutes. Assure adequate flushing by separating eyelids Eye Contact

with fingers. Consult an ophthalmologist immediately.

Skin Contact Remove contaminated clothing. Flush exsposed area with running water for at least 15 minutes.

Wash skin with plenty of soap and water. Consult a physician. Chemically decontaminate

clothing and launder before reuse.

Inhalation Remove victim promptly to fresh air. Administer artificial respiration if victim is not breathing.

If breathing is difficult give oxygen. Consult a physician.

If person is conscious wash out mouth with water to remove residual compound. Consult a Ingestion

physician immediately.

Additional Provide supportive treatment. No specific antidote exists.

5. Fire Fighting Measures

LEL Unknown

UEL Unknown

Flash Point

Auto Ignition Temp

Unknown. Unknown

Extinguishing Media

Water, carbon dioxide, or dry chemical as appropriate to the surrounding

Explosion Hazard

Explosive characteristics of this material are not known to have been

investigated.

Special Procedures

Evacuate personnel to a safe area. Fire fighters should use protective clothing and a self-contained breathing apparatus. Follow DOT emergency

guide number 53 f or solids (or 55 for liquids)(1991 Emergency Response

Guidebook, DOT P 5800.5).

Hazardous Combustion Byproducts

Thermal decomposition may produce toxic by-products or fumes such as carbon monoxide and carbon dioxide and nitrogen oxides. Since specific products of combustion are unknown, as a precaution, assume they are

hazardous.

Additional Information

6. Accidental Release Measures

Evacuate the area. Wear a respirator (or if properly trained, a self-contained breathing apparatus), rubber boots, and heavy rubber gloves. Wear disposable coveralls and discard after use. Avoid raising aerosols by promptly covering the spilled compound with wet paper towels. Pick up material with additional towels, place in a bag or barrel, and hold for waste disposal. After compound pick-up is complete, ventilate area and wash spill site. Dispose of contaminated clean-up materials properly.



Executive Plaza North, Room 831

6130 Executive Blvd., Rockville, MD 20852

NSC: 676693

CAS: 156274-19-0

Supplier MSDS N

Create Date: Last Revised: 6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

7. Handling and Storage

Special Handling

This material is an investigational substance. Hazards associated with exposure to this material are unknown. Handling of solids or solutions should be carried out with extreme care to avoid personal exposure. This material should be handled only by those trained in the handling of potentially hazardous material.

Special Storage

None

Additional Information

Wash thoroughly after handling.

8. Exposure Controls and Personal Protection

Goggles

Wear chemical safety goggles when handling this material.

Gloves

Wear rubber or latex gloves (not polyvinylchloride) when handling this material.

Laboratory coat or apron and sleeves are also recommended.

Respirator

Wear a NIOSH-MSHA approved respirator. Supplied-air packs could alternatively be used by personnel trained in the use of this equipment.

Safety Station

Safety shower and eye wash should be accessible.

Apparel

Wear a protective laboratory coat or a Tyvek suit with shoe covers during bulk

operations.

Ventillation

Operations should be conducted in a chemical fume hood, glove box, or ventilated cabinet equipped with mechanical exhaust to the outside. General

room ventilation should meet good laboratory design standards.

Additional Information

The personal protective equipment listed above should be worn when handling this material. Consider engineering and operational controls to minimize

exposure potential.

9. Physical and Chemical Properties

Characteristics

Unknown

Additional Information

10. Stability and Reactivity

Chemical Stability

This material is stable under most conditions. Hazardous polymerization is not known to occur.

11. Toxicological Information

Toxicological properties of this compound have not yet been fully investigated



Executive Plaza North, Room 831 6130 Executive Blvd., Rockville, MD 20852

Supplier MSDS N

NSC: 676693

CAS: 156274-19-0

Create Date: Last Revised:

6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

12. Ecological Information

The ecological impact of this material is not yet known.

13. Disposal Considerations

Disposal

Observe all Federal, state, and local laws concerning the disposal of hazardous material or waste.

EPA Hazardous Waste Number

None

14. Transportation Information

Shipping of samples of this material should adhere to current regulations.

15. Regulatory Information

All Federal, state, and local regulations should be observed.

16. Other Information

Disclaimer

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Page 1 of 4

MATERIAL SAFETY DATA SHEET

Developmental Therapeutics Program, DCT National Cancer Institute Executive Plaza North, Room 831 6130 Executive Boulevard

NSC 606985

Revision Date: October 5, 1993

SECTION I. MATERIAL IDENTIFICATION

Common Name: NSC 606985

Rockville, Maryland 20852

CAS: Not available

Molecular Weight: 442

Molecular Formula: C22H19N3O5.HC1

Other Designations: NSC 606985

SECTION II. INGREDIENTS AND HAZARDS

Ingredient Name

Percent

Exposure Limits

NSC 606985

100%

NOT YET ESTABLISHED

Toxicity Data:

In Vitro Activity:

NSC 606985 has been designated as a potent toxin based on its inhibition of cell growth in vitro; it shows an MLGI $_{50}$ against cancer cells of $<10^{-7.4}$ molar in the NCI tumor panel screen. As a precaution the compound must be handled as a potent toxin.

In Vivo Activity:

Not yet established.

SECTION III. PHYSICAL DATA

Appearance & Odor:

MP: N/A

Solubility (%): UNKNOWN

BP: N/A

Page 2 of 4

SECTION IV. FIRE AND EXPLOSION DATA

Flash Point: UNKNOWN

Flammability Limits: LEL %: UNKNOWN

Autoignition Temperature: UNKNOWN

UEL : UNKNOWN

Extinguishing Media: Water, carpon dioxide, or dry chemical as appropriate

to the surrounding fire.

Unusual Fire or Explosion Hazards: No unusual fire or explosion hazard is known to exist.

Special Fire-fighting Procedures Evacuate personnel to a safe area. Fire fighters should use protective clothing and a self-contained breathing apparatus.

Hazardous Combustion Products: ts: Thermal decomposition may yield monoxide and other toxic substances. carbon Since

specific products of combustion are unknown, as a precaution, they should be assumed to be

hazardous.

SECTION V. REACTIVITY PATA

Compound Stability: Stability studies have not vet been carried out.

Chemical Incompatibilities: Unknown at this time

Conditions To Avoid: Unknown at this time

Hazardous Decomposition Products: Unknown at this time.

SECTION VI. HEALTH HAZARD INFORMATION

Summary of Risks: The carcinogenicity and teratogenicity of NSC 606985 are unknown.

Signs & Symptoms of Overexposure: The effects of overexposure to this drug in the workplace are not known. It is anticipated that acute or chronic overexposure could lead to damage of bone marrow, liver, kidney, lymphoid tissue, GI tract and possibly reproductive organs or could be fatal. NSC 606985 is cytotoxic and will produce severe toxic effects to rapidly dividing tissues upon overexposure.

Acute Effects: UNKNOWN Chronic Effects: UNKNOWN

Primary Entry Routes: Inhalation, ingestion, and skin and/or eye contact.

Target Organs: The target organs of toxicity in animals are not known at this

time.

Page 3 of 4

MATERIAL S DATA SHEET

Developmental Therapeutics Program, DCT National Cancer Institute Executive Plaza North, Room 831 6130 Executive Boulevard Rockville, Maryland 20852

NSC 606985

Revision Date: October 5, 1993

Medical Conditions Which May Be Aggravated By Contact: UNKNOWN

For Eye Contact: Immediately flush eyes with copious amounts of water for at least 15 minutes. Consult an ophthalmologist.

For Skin Contact: Remove contaminated clothing. Wash skin with plenty of soap and water. Consult a physician. Chemically decontaminate clothing and then launder before reuse or incinerate.

For Inhalation: Remove victim promptly to clean air. If victim is not breathing, administer artificial respiration. If breathing is difficult give oxygen. Consult a physician.

tion: Remove residual drug. Consult a physician. Provide supportive treatment. No specific antidote exists. For Ingestion:

SECTION VII. SPILL, LEAK AND DISPOSAL PROCEDURES

Cleanup of Spills/Leaks:

These should be conducted according to the "DTP (NCI) Generic Safe Handling Procedures for Potent Toxic Drugs" (10/13/92): Evacuate area. Wear self-contained breathing apparatus, rubber boots, and heavy rubber gloves. Wear disposable coveralls and discard after use. Avoid raising aerosols by promptly covering the spilled compound with damp paper towels. Pick up compound with additional towels, place in a bag, and hold for waste disposal. Sodium hypochlorite may degrade NSC 606985 to relatively nontoxic derivatives. Expose the contaminated area to the bleach solution for one hour. Afterwards, first wipe the area with paper towels soaked in bleach solution and then with paper towels wet with water. Ventilate area after compound pick-up and decontamination is complete. Dispose of contaminated clean-up materials properly.

Waste Management/Disposal:

Incineration, at a temperature not less than 1000°C, is the recommended method of disposal. Observe all Federal, state, and local laws concerning the disposal of hazardous material or waste. Dissolve solids in a 10% solution of sodium hypochlorite. Add water miscible organic solvent to drug solutions and then treat with the bleach solution. Contaminated glassware, syringes, wipe-up naterials, etc., should also be flushed with the bleach solution to reduce residues of toxic materials.

Page 4 of 4

SECTION VIII. SPECIAL PROTECTION INFORMATION

SHRADER 539CC

Personal Protective Equipment:

Goggles:

Wear chemical safety goggles when handling NSC 606985.

Gloves:

Wear rubber or latex gloves, not polyvinylchloride, when handling

NSC 606985.

Other:

Respirator: Wear NIOSH-MSHA approved respirator Wear protective laboratory coat.

Workplace Considerations:

Ventilation: Laboratory operations should be conducted in a chemical fume hood, glove box, or ventilated cabinet equipped with filtered

mechanical exhaust to the outside.

Safety Stations: Safety shower and eye bath should be accessible.

The personal protective equipment listed above should be worn at all times when handling NSC 606985. Avoid contact and inhalation. Avoid prolonged or repeated exposure. Wash thoroughly after hand ing.

SECTION IX. SPECIAL PRECAUTIONS

Storage Segregation: Store in a tightly-closed container, protected from light, at -20°C. In case of hygroscopic compounds, store over drierite. of a secondary container is recommended.

Other Precautions: The user should be made aware that NSC 606985 is an investigational substance. It is a highly potent cytotoxic agent. Handling as a solid or a solution should be carried but with extreme care to avoid personal exposure. Hazards associated with exposure to NSC 606985 may as yet be unknown. This material should be handled only by those trained in the handling of potentially hazardous material.

For Non-Emergency Information:

Decontamination Procedures 301-496-8780

Material Safety Data Sheets 301-496-8795

Toxicity Data 301-496-8777 Chief, Pharmaceutical Resources Branch

Project Officer, Drug Synthesis And Chemistry Branch

Chief, Toxidology Branch

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Executive Plaza North, Room 831

6130 Executive Blvd., Rockville, MD 20852

Supplier MSDS N

NSC: 268665

CAS: --

Create Date: Last Revised:

6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

1. Company Identification

In Case of Emergency Call:

Decontamination Procedures

Material Safety Data Sheets

Toxicity Data

Additional Information

Pharmaceutical Resources Branch, (301)-496-8780

Drug Synthesis and Chemistry Branch, (301)-496-8795

Toxicology Branch,(301)-496-8777

2. Chemical Product and Composition

Chemical Name

Common Name

Synonyms

Molecular Weight

514

Molecular Formula

C21H21N3O5Sn

Composition

This material consists solely of 268665

Additional Information

3. Hazards Identification

RTECS Index

Summary of Risks

To the best of our knowledge, the toxicological properties of this material

have not yet been fully investigated.

Known Carcinogen

This compound is not listed in the OSHA, IARC or NTP literature as a

carcinogen or cancer suspect agent.

Medical Conditions Aggravated by

Contact

Unknown

Target Organs

The target organs of toxicity are not known at this time.

Relevant Routes of Entry

Inhalation, ingestion, and skin/eye contact.

Acute Effects

The acute effects of exposure to this material in the workplace are not

known at this time.

Chronic Effects

The chronic effects of exposure to this material in the workplace are not

known at this time.

Eye Contact

The effects of eye contact with this material are unknown.

Skin Contact

Inhalation

The effects of skin contact with this material are unknown.

The effects of inhalation of this material are unknown.

Ingestion

The effects of ingestion of this material are unknown.



Executive Plaza North, Room 831

6130 Executive Blvd., Rockville, MD 20852

CAS: --

NSC:

Create Date:

6/28/1995 7:46:48 AM

268665

Last Revised:

11/18/1997 1:59:54 PM

Known Hazards

None known

Additional Information

Supplier MSDS N

4. First Aid Measures

Eye Contact Flush with running water for at least 15 minutes. Assure adequate flushing by separating eyelids

with fingers. Consult an ophthalmologist immediately.

Skin Contact Remove contaminated clothing. Flush exsposed area with running water for at least 15 minutes.

Wash skin with plenty of soap and water. Consult a physician. Chemically decontaminate

clothing and launder before reuse.

Inhalation Remove victim promptly to fresh air. Administer artificial respiration if victim is not breathing.

If breathing is difficult give oxygen. Consult a physician.

Ingestion If person is conscious wash out mouth with water to remove residual compound. Consult a

physician immediately.

Additional Provide supportive treatment. No specific antidote exists.

5. Fire Fighting Measures

LEL Unknown

IIII III

Flash Point

Unknown

UEL Unknown

Auto Ignition Temp Unknown

Extinguishing Media

Water, carbon dioxide, or dry chemical as appropriate to the surrounding

fire.

Explosion Hazard

Explosive characteristics of this material are not known to have been

investigated.

Special Procedures

Evacuate personnel to a safe area. Fire fighters should use protective clothing and a self-contained breathing apparatus. Follow DOT emergency

guide number 53 f or solids (or 55 for liquids)(1991 Emergency Response

Guidebook, DOT P 5800.5).

Hazardous Combustion Byproducts

Thermal decomposition may produce toxic by-products or fumes such as carbon monoxide and carbon dioxide and nitrogen oxides. Since specific products of combustion are unknown, as a precaution, assume they are

hazardous.

Additional Information

6. Accidental Release Measures

Evacuate the area. Wear a respirator (or if properly trained, a self-contained breathing apparatus), rubber boots, and heavy rubber gloves. Wear disposable coveralls and discard after use. Avoid raising aerosols by promptly covering the spilled compound with wet paper towels. Pick up material with additional towels, place in a bag or barrel, and hold for waste disposal. After compound pick-up is complete, ventilate area and wash spill site. Dispose of contaminated clean-up materials properly.



Executive Plaza North, Room 831

6130 Executive Blvd., Rockville, MD 20852

NSC: 268665

CAS: --

Supplier MSDS N

Create Date: Last Revised: 6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

7. Handling and Storage

Special Handling

This material is an investigational substance. Hazards associated with exposure to this material are unknown. Handling of solids or solutions should be carried out with extreme care to avoid personal exposure. This material should be handled only by those trained in the handling of potentially hazardous material.

Special Storage

None

Additional Information

Wash thoroughly after handling.

8. Exposure Controls and Personal Protection

Goggles

Wear chemical safety goggles when handling this material.

Gloves

Wear rubber or latex gloves (not polyvinylchloride) when handling this material.

Laboratory coat or apron and sleeves are also recommended.

Respirator

Wear a NIOSH-MSHA approved respirator. Supplied-air packs could alternatively be used by personnel trained in the use of this equipment.

Safety Station

Safety shower and eye wash should be accessible.

Apparel

Wear a protective laboratory coat or a Tyvek suit with shoe covers during bulk

operations.

Ventillation

Operations should be conducted in a chemical fume hood, glove box, or ventilated cabinet equipped with mechanical exhaust to the outside. General

room ventilation should meet good laboratory design standards.

Additional Information

The personal protective equipment listed above should be worn when handling this material. Consider engineering and operational controls to minimize

exposure potential.

9. Physical and Chemical Properties

Characteristics

Unknown

Additional Information

10. Stability and Reactivity

Chemical Stability

This material is stable under most conditions. Hazardous polymerization is not known to occur.

11. Toxicological Information

Toxicological properties of this compound have not yet been fully investigated



Executive Plaza North, Room 831 6130 Executive Blvd., Rockville, MD 20852

Supplier MSDS N

NSC: 268665

CAS: --

Create Date: Last Revised:

6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

12. Ecological Information

The ecological impact of this material is not yet known.

13. Disposal Considerations

Disposal

Observe all Federal, state, and local laws concerning the disposal of hazardous material or waste.

EPA Hazardous Waste Number

None

14. Transportation Information

Shipping of samples of this material should adhere to current regulations.

15. Regulatory Information

All Federal, state, and local regulations should be observed.

16. Other information

Disclaimer

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SDS Number 1283 Material HYCAMTIN INJECTABLE Approved/Revised 02-Feb-2005

Version 19

SAFETY DATA SHEET



IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material

HYCAMTIN INJECTABLE

Synonyms

HYCAMTIN INFUSION 1 MG/3 ML * HYCAMTIN INJECTION 1 MG/3 ML * HYCAMTIN INJECTION 4 MG/5 ML * TOPOTECAN, FORMULATED PRODUCT * NDC NO. 0007-4200-01 * NDC NO. 0007-4200-05 * NDC NO. 0007-4200-40 * NDC NO. 0007-4200-41 * NDC NO. 0007-4200-42 * NDC NO. 0007-4200-43 * NDC NO. 0007-4200-51 * NDC NO. 0007-4200-55 * NDC NO. 0007-4200-90 * NDC NO. 0007-4201-01 * NDC NO. 0007-4201-05 * NDC NO. 0007-4200-44 * NDC NO. 0007-4201-02 * NDC NO. 0007-4201-11

Company Name

GlaxoSmithKline, Corporate Environment, Health & Safety

980 Great West Road

Brentford, Middlesex

TW8 9GS UK

UK General Information: Transport Emergency (EU)

+44-20-8047-5000 +44-1865-407333

Medical Emergency
Information and Advice:

+1-612-221-3999, Ext 221 US number, available 24 hours

Multi-language response

GlaxoSmithKline, Corporate Environment, Health & Safety

2200 Renaissance Blvd, Suite 105

King of Prussia, PA

19406 US

US General Information:

+1-888-825-5249

Transport Emergency (non EU)

+1-703-527-3887

US number, available 24 hours Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CA	SRN Pe	rcentage
TOPOTECAN	119	413-54-6 < 1	0
NON-HAZARDOUS INGREDIENTS	Una	assigned >90	0

3. HAZARDS IDENTIFICATION

Fire and Explosion

This product is classified as non-flammable.

Health

Exposure might occur via skin; eyes; ingestion.

Caution - Potent pharmaceutical agent. May cause cancer. May produce adverse effects on the development of human offspring. Possible effects of overexposure in the workplace include: nausea; vomiting; diarrhoea; bone

marrow toxicity.

Health effects information is based on hazards of components.

Approved/Revised 02-Feb-2005

Version 19

Material HYCAMTIN INJECTABLE

Environment

No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES

Ingestion

Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give

plenty of water to drink. Obtain medical attention.

Inhalation

Physical form suggests that risk of inhalation exposure is negligible.

Skin Contact

Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or

Eye Contact

Wash immediately with clean and gently flowing water. Continue for at least

15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment

Medical treatment in cases of overexposure should be treated as an

overdose of a cytotoxic agent.

Medical Conditions Caused or Aggravated

by Exposure

None for occupational exposure.

Health Surveillance **Procedures**

The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should undergo appropriate health surveillance that may include symptom enquiry, clinical examination and monitoring of lead organ effects (e.g. full blood counts). In the event of overexposure, individuals should receive post exposure health surveillance focused on the most likely health effects (e.g. full blood

counts).

Antidotes

No specific antidotes are recommended.

FIRE-FIGHTING MEASURES

Fire and Explosion Hazards

Not expected for the product, although the packaging is combustible.

Extinguishing Media

Water is recommended for fires involving packaging.

Special Firefighting **Procedures**

For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.

Hazardous Combustion Products

Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions

For all spills, isolate the spill area, restrict access, post the area for a carcinogen and immediately implement emergency procedures for cleanup and control of occupational carcinogens. Wear protective clothing and equipment consistent with the degree of hazard.

Environmental Precautions

Do not allow this material to enter surface drainage systems, sewers and poorly ventilated areas.

Approved/Revised 02-Feb-2005

Version 19

Material HYCAMTIN INJECTABLE

Clean-up Methods

Spread an inert absorbent on the spill and place in a suitable, properly

labelled container for recovery or disposal.

Decontamination Procedures Surfaces should be decontaminated so that potential exposures do not exceed the hygiene guide specified in Section 8 of this SDS. The pH of the collected wash waters should be adjusted using base, such as sodium hydroxide, to a pH greater than 8; commercial bleach solution, containing approximately 5% hypochlorite, should then be added to the waste water. Microgram levels of surface contamination can be visualised using ultraviolet light.

7. HANDLING AND STORAGE

HANDLING

General Requirements

Isolation or enclosure is recommended to control exposure to this material.

STORAGE

The recommended temperature for storage is 15-30 °C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT

TOPOTECAN

GSK Occupational Hazard Category

4

GSK Occupational Exposure Limit

0.03 MCG/M3 (8 HR TWA)

CARCINOGEN, REPRODUCTIVE HAZARD, HIGHLY POTENT

ENGINEERING CONTROLS

Containment

Open handling may result in overexposure. Consider use of enclosures.

Administrative

Entry to the working area should be controlled.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection

Wear approved safety glasses with side shields if eye contact is possible.

Gloves

The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Glove selection must take into account any solvents and other hazards present. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Care must be exercised if no data are available and further guidance should be sought from your local safety department. Glove selection must take into account any solvents and other hazards

present

Respirators

Respiratory protective equipment (RPE) is not required for normal handling

of this material.

Other Equipment or Procedures Wear appropriate clothing to avoid skin contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form

Lyophilised powder.

pH of Aqueous Solutions

3

10. STABILITY AND REACTIVITY

Stability

This product is expected to be stable.

Conditions to Avoid

None for normal handling of this product.

Approved/Revised 02-Feb-2005

Version 19

Material HYCAMTIN INJECTABLE

11. TOXICOLOGICAL INFORMATION

Oral Toxicity Toxicity might occur following ingestion.

Inhalation Toxicity No studies have been conducted.

Skin Effects Irritation is not expected following direct contact.

Eye Effects Irritation is not expected following direct contact with eyes.

Target Organ Effects Adverse effects might occur in the following organ(s) following

overexposure: bone marrow and formation of blood cells.

Sensitisation Potential for inducing allergic reactions via the dermal or respiratory route is

not known.

Genetic Toxicity Known or probable human mutagen.

Carcinogenicity Contains a component listed as a carcinogen by: (GSK). No components

are listed as carcinogens by: (IARC); (NTP); (US OSHA).

Reproductive Effects Contains components which have been classified as: Known or presumed

to cause toxicity in developing human offspring. Known or presumed to

impair fertility in human females.

Pharmacological Effects This preparation contains ingredient(s) with the following activity: a

cytotoxic agent.

white blood cell count; nausea; diarrhoea; vomiting; fatigue.

12. ECOLOGICAL INFORMATION

* Summary No information is available about the potential of this product to produce

adverse environmental effects. This material contains an active pharmaceutical ingredient that has been tested and which may be harmful if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted

prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided

below.

ECOTOXICITY

Aquatic

* Microtox Microtox is a general toxicity test which utilizes a sensitive marine photo

bacteria as the test species. This material contains an active

pharmaceutical ingredient that is not toxic to these microorganisms.

EC50: 102 mg/L, 15 Minutes

* Daphnid This material contains an active pharmaceutical ingredient that is harmful to

daphids.

EC50: 61.8 mg/L, 48 Hours, Daphnia magna, Static test

* Fish This material contains an active pharmaceutical ingredient that is harmful to

fish.

Adult Pimephales promelas, fathead minnow

EC50: 45.7 mg/L, 96 Hours, Static test

Adult Pimephales promelas, fathead minnow

NOEL: 25 mg/L, 96 Hours, Static test

MOBILITY

Approved/Revised 02-Feb-2005

Version 19

Material HYCAMTIN INJECTABLE

* Solubility This material contains an active pharmaceutical ingredient that for

environmental fate predictions has solubility in water.

* Adsorption This material contains an active pharmaceutical ingredient that is not likely

to adsorb to sludge or biomass if released directly to the environment. 2.28 Measured

Sludge Biomass

Distribution Coefficient

(log Kd):

* Partitioning This material contains an active pharmaceutical ingredient with

octanol/water partition coefficient data that suggests that for environmental

fate predictions the active pharmaceutical ingredient will not have the

tendency to distribute into fats.

PERSISTENCE/DEGRADATION

* Hydrolysis This material contains an active pharmaceutical ingredient that has been

shown to be chemically stable in water. Hydrolysis is unlikely to be a

significant depletion mechanism.

Half-Life, Neutral: 35 Years, Measured

* Photolysis This material contains an active pharmaceutical ingredient that has been

shown to be chemically unstable in water when exposed to light. Aqueous

photolysis may be a significant depletion mechanism.

Half-Life, Aqueous: 2.51 Minutes, Measured

* Biodegradation This material contains an active pharmaceutical ingredient that is not

readily biodegradable (as defined by 1993 OECD Testing Guidelines).

Aerobic - Ready

Percent Degradation: 0 %, 28 days, Batch activated sludge (BAS),

Residential sludge

DISPOSAL CONSIDERATIONS

Disposal

Recommendations

Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or

re-used. The recommended method of disposal is incineration.

Observe all local and national regulations when disposing of this product. Regulatory Requirements

TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Technical Name HYCAMTIN INJECTABLE

Proper Shipping Name Medicine, solid, toxic, nos

(HYCAMTIN INJECTABLE)

UN Number UN 3249

Class/Division 6.1 **Packing Group**

Risk Label(s) Class 6.1 Toxic



Approved/Revised 02-Feb-2005

Version 19

Material HYCAMTIN INJECTABLE

International Air Transport (IATA Requirements)

UNID Number

ID 8000

Proper Shipping

Consumer Commodity

Name/Description

ICAO/IATA Class/Division 9

Subsidiary Risk

None

Packing Group

Not applicable (use packing instruction 910).

Hazard Label(s)

Class 9



Limited Quantities

Quantities equal to or less than 0.5 kg per inner packaging are not subject to the full packaging and labelling requirements, although the appropriate shipping papers will be required.

International Maritime Transport (IMDG Requirements)

UN Number

UN 3249

Proper Shipping

Medicine, solid, toxic, nos

Name/Description

IMO Class/Division

6.1

Subsidiary Risk

None

Packing Group

III

Class Label(s)

Class 6.1 Toxic



Marine Pollutant Status

Not listed

Limited Quantities

Quantities equal to or less than 3 kg per inner packaging are not subject to the full packaging and labelling requirements, although the appropriate

shipping papers will be required.

Approved/Revised 02-Feb-2005

Material HYCAMTIN INJECTABLE

Version 19

US Domestic Transport (DOT Requirements)

Proper Shipping Name

Consumer Commodity, ORM-D

DOT Hazard Class/Division ORM-D

UN/NA Number

Not applicable.

Packing Group

Not applicable

US Emergency Response 151

Guide Number

Quantity Limitations

Quantities equal to or less than 0.25 kg per inner packaging are not subject to the full packaging and labelling requirements, although the appropriate shipping papers will be required.

European Ground Transport (ADR/RID Requirements)

Classification and

Not subject to ADR, see SP 601.

Labelling

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

* EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

Safety Phrase(s)

S23 - Do not breathe.

S25 - Avoid contact with eyes.

S26 - In case of contact with eyes, rinse immediately with plenty of water and

seek medical advice.

S29 - Do not empty into drains.

S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection. S38 - In case of insufficient ventilation, wear suitable respiratory equipment.

S53 - Avoid exposure - obtain special instructions before use.

S60 - This material and/or its container must be disposed of as hazardous

waste.

US OSHA Standard (29 CFR Part 1910.1200)

Classification

This product is classified as hazardous according to the OSHA Hazard

Communication Standard.

Other US Regulations

TSCA Status

Exempt

OTHER INFORMATION

References

GSK Hazard Determination

Date Approved/Revised 02-Feb-2005

SDS Version Number 19

SDS Sections Updated

Sections

ECOLOGICAL INFORMATION

Subsections

Activated Sludge Respiration

Adsorption

Algal

Algal Degradation Bioaccumulation Biodegradation

Daphnid

SDS Number 1283
Material HYCAMTIN INJECTABLE

Approved/Revised 02-Feb-2005

Version 19

SDS Sections Updated

Sections

ECOLOGICAL INFORMATION

Subsections

Distribution

Earthworm

Ecotoxicity

Fish

Hydrolysis

Microbial Growth Inhibition

Microtox

Mobility

Other Adverse Effects

Other Species - Aquatic

Other Species - Terrestrial

Partitioning

Persistence/Degradation

Photolysis Solubility Summary

Volatility

REGULATORY INFORMATION TRANSPORT INFORMATION

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.



Executive Plaza North, Room 831

6130 Executive Blvd., Rockville, MD 20852

Supplier MSDS N

NSC: 259968

CAS: 64755-14-2

Create Date: Last Revised: 6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

1. Company Identification

In Case of Emergency Call:

Decontamination Procedures

Material Safety Data Sheets

Toxicity Data

Additional Information

Pharmaceutical Resources Branch, (301)-496-8780

Drug Synthesis and Chemistry Branch, (301)-496-8795

Toxicology Branch, (301)-496-8777

2. Chemical Product and Composition

Chemical Name

BOUVARDIN (9CI)

Common Name

Synonyms

Molecular Weight

773

Molecular Formula

C40H48N6O10

Composition

This material consists solely of 259968

Additional Information

3. Hazards Identification

RTECS Index

Summary of Risks

To the best of our knowledge, the toxicological properties of this material

have not yet been fully investigated.

Known Carcinogen

This compound is not listed in the OSHA, IARC or NTP literature as a

carcinogen of dancer suspect agent.

Medical Conditions Aggravated by

Contact

Unknown

Target Organs

The target organs of toxicity are not known at this time.

Relevant Routes of Entry

Inhalation, ingestion, and skin/eye contact.

Acute Effects

The acute effects of exposure to this material in the workplace are not

known at this time.

Chronic Effects

The chronic effects of exposure to this material in the workplace are not

known at this time.

Eye Contact

The effects of eye contact with this material are unknown.

Skin Contact

The effects of skin contact with this material are unknown.

Inhalation

The effects of inhalation of this material are unknown.

Ingestion

The effects of ingestion of this material are unknown.



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6130 Executive Blvd., Rockville, MD 20852

259968 NSC:

CAS: 64755-14-2

Supplier MSDS N

Create Date: Last Revised:

6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

Known Hazards

TOX IVP

Additional Information

Toxic (TOM) - Avoid all contact. Use proper engineering controls and personal protective equipment when handling.

4. First Aid Measures

Flush with running water for at least 15 minutes. Assure adequate flushing by separating eyelids Eye Contact

with fingers. Consult an ophthal trologist immediately.

Skin Contact Remove contaminated clothing. Flush exsposed area with running water for at least 15 minutes.

Wash skin with plenty of soap and water. Consult a physician. Chemically decontaminate

clothing and launder before reuse.

Remove victim promptly to fresh air. Administer artificial respiration if victim is not breathing. Inhalation

If breathing is difficult give oxygen. Consult a physician.

If person is conscious wash out mouth with water to remove residual compound. Consult a Ingestion

physician immediately.

Provide supportive treatment. No specific antidote exists. Additional

5. Fire Fighting Measures

LEL Unknown

Flash Point

Unknown

UEL Unknown

Auto Ignition Temp Unknown

Extinguishing Media

Water, carbon dioxide, or dry chemical as appropriate to the surrounding

Explosion Hazard

Explosive characteristics of this material are not known to have been

investigated.

Special Procedures

Evacuate personnel to a safe area. Fire fighters should use protective clothing and a self-contained breathing apparatus. Follow DOT emergency guide number 53 for solids (or 55 for liquids)(1991 Emergency Response Guidebook, DOT P 5800.5).

Hazardous Combustion Byproducts

Thermal decomposition may produce toxic by-products or fumes such as carbon monoxide and carbon dioxide and nitrogen oxides. Since specific products of combustion are unknown, as a precaution, assume they are hazardous.

Additional Information

6. Accidental Release Measures

Evacuate the area. Wear a respirator (or if properly trained, a self-contained breathing apparatus), rubber boots, and heavy rubber gloves. Wear disposable coveralls and discard after use. Avoid raising aerosols by promptly covering the spilled compound with wet paper towels. Pick up material with additional towels, place in a bag or barrel, and hold for waste disposal. After compound pick-up is complete, ventilate area and wash spill site.

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CAS: 64755-14-2

Supplier MSDS N

Create Date: Last Revised: 6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

Dispose of contaminated clean-up materials properly.

7. Handing and Storage

Special Handling

This material is an investigational substance. Hazards associated with exposure to this material are unknown. Handling of solids or solutions should be carried out with extreme sare to avoid personal exposure. This material should be handled only by those trained in the handling of potentially hazardous material.

Special Storage

Freeze (FRZ) between -18 and -22 degrees Celcius

Additional Information

Wash thoroughly after handling.

8. Exposure Controls and Personal Protection

Goggles

Wear chemical safety goggles when handling this material.

Gloves

Wear rubber or lates gloves (not polyvinylchloride) when handling this material. Laboratory coat or apron and sleeves are also recommended.

Respirator

Wear a NIOSH-MSHA approved respirator. Supplied-air packs could alternatively be used by personnel trained in the use of this equipment.

Safety Station

Safety shower and eye wash should be accessible.

Apparel

Wear a protective laboratory coat or a Tyvek suit with shoe covers during bulk

operations.

Ventillation

Operations should be conducted in a chemical fume hood, glove box, or ventilated cabinet emipped with mechanical exhaust to the outside. General

room ventilation should meet good laboratory design standards.

Additional Information

The personal protective equipment listed above should be worn when handling this material. Consider engineering and operational controls to minimize

exposure potential.

9. Physical and Chemical Properties

Characteristics

Unknown

Additional Information

10. Stability and Reactivity

Chemical Stability

This material is stable under most conditions. Hazardous polymerization is not known to occur.

11. Toxicological Information

In-Vitro (Vivo) Potent (IVP)- This compound has been designated as a potential toxin based upon preclinical data from the National Cancer Institute screening program

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Developmental Therapeutics Program, National Cancer Institute

Executive Plaza North, Room 831

6130 Executive Blvd., Rockville, MD 20852

Supplier MSDS N

NSC: 259968

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Create Date: Last Revised:

6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

12. Ecological Information

The ecological impact of this material is not yet known.

13. Disposal Considerations

Disposal

Observe all Federal, state, and local laws concerning the disposal of hazardous material or waste.

EPA Hazardous Waste Number

14. Transportation Information

Shipping of samples of this material should adhere to current regulations.

UN 2811, TOXIC SOLID, ORGANIC, N.O.S., (BOUVARDIN), 6.1, III

15. Regulatory Information

All Federal, state, and local regulations should be overved.

16. Other Information

Disclaimer

The information in this document was compiled primarily from secondary sources. The information is believed to be correct and accurate, but no independent verification has been performed. No warranty is expressed or implied with

Executive Plaza North, Room 831

6130 Executive Blvd., Rockville, MD 20852

Supplier MSDS N

NSC: 259969

CAS: 64725-24-2

Create Date: Last Revised:

6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

1. Company Identification

In Case of Emergency Call:

Decontamination Procedures

Material Safety Data Sheets

Toxicity Data

Additional Information

Pharmaceutical Resources Branch, (301)-496-8780

Drug Synthesis and Chemistry Branch,(301)-496-8795

Toxicology Branch,(301)-496-8777

2. Chemical Product and Composition

Chemical Name

BOUVARDIN, 5-(N-METHYL-L-TYROSINE)- (9CI)

Common Name

Synonyms

Molecular Weight

757

Molecular Formula

C40H48N609

DEOXYBOUVARDIN

Composition

This material consists solely of 259969

Additional Information

3. Hazards Identification

RTECS Index

Summary of Risks

To the best of put knowledge, the toxicological properties of this material

have not yet been fully investigated.

Known Carcinogen

This compound is not listed in the OSHA, IARC or NTP literature as a

carcinogen or cancer suspect agent.

Medical Conditions Aggravated by

Contact

Unknown

Target Organs

The target organs of toxicity are not known at this time.

Relevant Routes of Entry

Inhalation, ingestion, and skin/eye contact.

Acute Effects

The acute effects of exposure to this material in the workplace are not

known at this time.

Chronic Effects

The chronic effects of exposure to this material in the workplace are not

known at this time.

Eye Contact

The effects of eye contact with this material are unknown.

Skin Contact

The effects of skin contact with this material are unknown.

Inhalation

The effects of thatation of this material are unknown.

Ingestion

The effects of agestion of this material are unknown.

Executive Plaza North, Room 831

6130 Executive Blvd., Rockville, MD 20852

Supplier MSDS N

NSC: 259969

CAS: 64725-24-2

Create Date:

6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

Last Revised:

Known Hazards

TOX IVP

Additional Information

Toxic (TOX) - Avoid all contact. Use proper engineering controls and

personal projective equipment when handling.

4. First Aid Measures

Eye Contact Flush with running water for at least 15 minutes. Assure adequate flushing by separating eyelids

with fingers. Consult an ophthalmplogist immediately.

Remove contaminated clothing. Flush exsposed area with running water for at least 15 minutes. Wash skin with plenty of soap and water. Consult a physician. Chemically decontaminate Skin Contact

clothing and launder before reuse

Remove victim promptly to fresh air. Administer artificial respiration if victim is not breathing. Inhalation

If breathing is difficult give oxygen. Consult a physician.

If person is conscious wash out mouth with water to remove residual compound. Consult a Ingestion

physician immediately.

Additional Provide supportive treatment. No specific antidote exists.

5. Fire Fighting Measures

LEL Unknown

UEL Unknown

Flash Point

Unknown

Auto Ignition Temp Unknown

Extinguishing Media

Water, carbon dioxide, or dry chemical as appropriate to the surrounding

Explosion Hazard

Explosive characteristics of this material are not known to have been

investigated.

Special Procedures

Evacuate personnel to a safe area. Fire fighters should use protective clothing and self-contained breathing apparatus. Follow DOT emergency

guide number 33 f or solids (or 55 for liquids)(1991 Emergency Response

Guidebook, DOTP 5800.5).

Hazardous Combustion Byproducts

Thermal decomposition may produce toxic by-products or fumes such as carbon monoxide and carbon dioxide and nitrogen oxides. Since specific

products of combistion are unknown, as a precaution, assume they are

hazardous.

Additional Information

6. Accidental Release Measures

Evacuate the area. Wear a respirator (or if properly trained, a self-contained breathing apparatus), rubber boots, and heavy rubber gloves. Wear disposable coveralls and discard after use. Avoid raising aerosols by promptly covering the spilled compound with wet paper towels. Pick up material with additional towels, place in a bag or barrel, and hold for waste disposal. After compound pick-up is complete, ventilate area and wash spill site.

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Developmental Therapeutics Program, National Cancer Institute

Executive Plaza North, Room 831

6130 Executive Blvd., Rockville, MD 20852

Supplier MSDS N

Dispose of contaminated clean-up materials properly.

NSC: 259969

CAS: 64725-24-2

Create Date: Last Revised:

6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

7. Handing and Storage

Special Handling This material is an investigational substance. Hazards associated with exposure

to this material are unknown. Handling of solids or solutions should be carried out with extreme care to avoid personal exposure. This material should be

handled only by these trained in the handling of potentially hazardous material.

Special Storage

Freeze (FRZ) between -18 and -22 degrees Celcius

Additional Information

Wash thoroughly after handling.

8. Exposure Controls and Personal Protection

Goggles Wear chemical sately goggles when handling this material.

Gloves Wear rubber or latek gloves (not polyvinylchloride) when handling this material.

Laboratory coat or apron and sleeves are also recommended.

Respirator Wear a NIOSH-MSHA approved respirator. Supplied-air packs could

alternatively be used by personnel trained in the use of this equipment.

Safety Station Safety shower and sye wash should be accessible.

Apparel Wear a protective laboratory coat or a Tyvek suit with shoe covers during bulk

operations.

Ventillation

Operations should be conducted in a chemical fume hood, glove box, or ventilated orbinet equipped with mechanical exhaust to the outside. General

room ventilation should meet good laboratory design standards.

Additional Information The personal protective equipment listed above should be worn when handling

this material. Consider engineering and operational controls to minimize

exposure potential.

9. Physical and Chemical Properties

Characteristics

Unknown

Additional Information

10. Stability and Reactivity

Chemical Stability

This material is stable under most conditions. Hazardous polymerization is not

known to occur.

11. Toxicological Information

In-Vitro (Vivo) Potent (IVP)- This compound has been designated as a potential toxin based upon preclinical data from the National Cancer Institute screening program

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Developmental Therapeutics Program, National Cancer Institute

Executive Plaza North, Room 831

NSC: 259969

CAS: 64725-24-2

Supplier MSDS N

Create Date: Last Revised: 6/28/1995 7:46:48 AM 11/18/1997 1:59:54 PM

12. Ecological Information

The ecological impact of this material is not yet known.

6130 Executive Blvd., Rockville, MD 20852

13. Disposal Considerations

Disposal

Observe all fideral, state, and local laws concerning the disposal of hazardous material or waste.

EPA Hazardous Waste Number

14. Transportation Information

Shipping of samples of this material should adhere to current regulations.

UN 2811, TOXIC SOLID, ORGANIC, N.O.S., (DEOXYBOUVARDIN), 6.1, III

15. Regulatory Information

All Federal, state, and local regulations should be observed.

16. Other Information

Disclaimer

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SAIC / Frederick P.O. Box B Frederick, Maryland 21702

Date:	Man +, 2001
To:	O Scott Keining
Location:	blog 426
Phone#	
Fax#	6619

FROM: IN VIVO CARCINOGENESIS PROGRAM
BUILDING 539 3RD FLOOR
FREDERICK, MARYLAND 21702
PHONE # (301) 846-1270
FAX # (301) 846-1293

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